K030740

510(k) Summary - Tina-quant® D-Dimer Test System

APR 01 2003

Introduction	According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence
Submitter name, address, contact	Roche Diagnostics Corporation 9115 Hague Rd Indianapolis IN 46250 (317) 521-3831 Contact person: Sherri L. Coenen Date prepared: March 7, 2003
Device Name	Proprietary name: Tina-quant® D-Dimer Test System Common name: D-Dimer Test System Classification name: Fibrinogen/Fibrin Degradation Products Assay
Device description	The Tina-quant® D-Dimer Test system is a particle enhanced immunoturbidimetric assay. Latex particles are coated with monoclonal antibodies to the D-Dimer epitope. The antigen/antibody complexes produced by the addition of samples containing D-Dimer lead to an increase in turbidity.
Intended use	Immunoturbidimetric assay for the in vitro quantitative determination of fibrin degradation products including D-Dimer and X-oligomers in plasma.
Predicate Device	We claim substantial equivalence to the currently marketed Tina-quant® D-Dimer Test System. (K002706 and K011143).

510(k) Summary - COBAS Integra Creatinine plus ver.2,
continued

Reagent Summary

The following table describes the similarities and differences between the Tina-quant® D-Dimer Test System and the predicate device.

Topic	Tina-quant® D-dimer on Roche Hitachi (K002706)	Tina-quant® D-dimer on COBAS Integra (K011143)	Tina-quant® D-dimer (Modified Device)
Intended Use	Immunoturbidimetric assay for the in vitro quantitative determination of fibrin degradation products including D-Dimer and X-oligomers.	The cassette COBAS Integra Tina-quant® D-Dimer contains an in vitro diagnostic reagent system intended for use on COBAS Integra systems for the quantitative immunological determination of fibrin degradation products (D-Dimer and X-oligomers) in plasma	Same
Method	Particle enhanced Immunoturbidimetric	Same	Same
Sample type	Citrated plasma	Same	Citrated plasma Li-heparin plasma
Measuring range	0.15 - 9.0 µg FEU/ml	Same	Same
Expected values	< 0.5 µg FEU/ml	Same	Same

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Sherri L. Coenen
Regulatory Submissions, Centralized Diagnostics
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, Indiana 46250-0457

APR 01 2003

Re: k030740
Trade/Device Name: Tina-quant® D-Dimer Test System
Regulation Number: 21 CFR § 864.7320
Regulation Name: Fibrinogen/Fibrin Degradation Products Assay
Regulatory Class: II
Product Code: GHH
Dated: March 7, 2003
Received: March 10, 2003

Dear Ms. Coenen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): N/A K030740

Device Name: Tina-quant® D-Dimer Test System

Indications For Use:

Immunoturbidimetric assay for the in vitro quantitative determination of fibrin degradation products including D-Dimer and X-oligomers in plasma.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___√___ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K030740